Amendments

In the Claims

As amended, Claims 1-16 and 18-22 are pending. Claims 1-16 stand allowed. Claim 17 has been canceled. Claims 18-22 are amended.

CLAIMS

1. (Original) A system for preparing particles comprising:

a solution source comprising an effective ingredient;

a vessel for holding a cryogenic liquid; and

an insulating nozzle having an end and a tip, wherein the end of the insulating nozzle is connected to the solution source and the tip is placed at or below the level of the cryogenic liquid.

2. (Original) The system recited in claim 1, wherein the effective ingredient is a pharmaceutical.

3. (Original) The system recited in claim 2, wherein the effective ingredient is chosen from the group consisting of proteins, peptides, albuterol sulfate, terbutaline sulfate, diphenhydramine hydrochloride, chlorpheniramine maleate, loratidine hydrochloride, fexofenadine hydrochloride, phenylbutazone, nifedipine, carbamazepine, naproxen, cyclosporin, betamethosone, danazol, dexamethasone, prednisone, hydrocortisone, 17 beta-estradiol, ketoconazole, mefenamic acid, beclomethasone, alprazolam, midazolam, miconazole, ibuprofen, ketoprofen, prednisolone, methylprednisone, phenytoin, testosterone, flunisolide, diflunisal, budesonide, fluticasone; insulin, glucagon-like peptide, C-Peptide, erythropoietin, calcitonin, human growth hormone, leutenizing hormone, prolactin, adrenocorticotropic hormone, leuprolide, interferon alpha-2b, interferon beta-1a, sargramostim, aldesleukin, interferon alpha-2a, interferon alpha-n3, $alpha_1$-proteinase inhibitor; etidronate, nafarelin, chorionic gonadotropin, prostaglandin E2, epoprostenol, acarbose, metformin, or desmopressin,

cyclodextrin, antibiotics; and the pharmacologically acceptable organic and inorganic salts or metal complexes thereof.

4. (Original) The system recited in claim 1, wherein the solution source further comprises water, at least one organic solvent, or a combination thereof.

5. (Original) The system recited in Claim 4, wherein the organic solvent is selected from the group consisting of water miscible solvents and non-water miscible solvents.

6. (Original) The system recited in Claim 5 wherein the organic solvent is selected from the group consisting of ethanol, methanol, tetrahydrofuran, acetonitrile, acetone, tert-butyl alcohol, dimethyl sulfoxide, N,N-dimethyl formamide, diethyl ether, methylene chloride, ethyl acetate, isopropyl acetate, butyl acetate, propyl acetate, toluene, hexanes, heptane, pentane, and combinations thereof.

7. (Original) The system recited in claim 1, wherein the solution source further comprises an excipient, an adjuvant, an absorption enhancer, a release-rate controlling polymer, a stability enhancer, or combinations thereof.

8. (Original) The system recited in claim 1, wherein the cryogenic liquid is selected from the group consisting of carbon dioxide, nitrogen, ethane, propane, helium, argon, halocarbons or isopentane.

9. (Original) The system recited in claim 1, wherein the tip of the insulating nozzle has a diameter of between 1 micron and 1 centimeter.

10. (Original) A method for spray freezing comprising:

mixing an effective ingredient with a solution agent;

spraying the effective ingredient-solution agent mixture through an insulating nozzle located at or below the level of a cryogenic liquid, wherein the spray generates frozen particles.

11. (Original) The method recited in Claim 10 wherein the solution agent is selected from water, at least one organic solvent, or a combination thereof.

12. (Original) The method recited in claim 10, further comprising collecting the frozen particles.

13. (Original) The method recited in claim 10, wherein the effective ingredient is a water soluble pharmaceutical or a poorly water soluble pharmaceutical.

14. (Original) The method recited in claim 10, further comprising drying the frozen particles to substantially remove the water.

15. (Original) The method recited in claim 14, wherein the frozen particles are dried in a fluidized bed with a gas cooled to below the melting point of the frozen particles.

16. (Original) A particle produced by the method recited in claim 10.

17. (Canceled).

18. (Currently amended) The particle recited in claim ~~17~~16, wherein the particle has a porosity of between 0 percent and 80 percent

19. (Currently amended) The particle recited in claim ~~17~~16, wherein the particle has a density between 0.1 g/mL and 5 g/mL.

20. (Currently amended)The particle recited in claim ~~17~~16, wherein the particle has an aerodynamic size distribution between 0.05 micron and 0.1 mm.

21. (Currently amended) The particle recited in claim ~~17~~16, wherein the particle has a surface area of from 0.5 m^2/g to 500 m^2/g.

22. (Currently amended) The particle recited in claim ~~17~~16, wherein the particle has a contact angle against water of from 0 degrees to 120 degrees, preferably from 0 to 50 degrees.